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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,615	01/03/2002	Stacie J. Casman	21402-233 (Cura533)	5238

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EXAMINER	
KEMMERER, ELIZABETH	

ART UNIT	PAPER NUMBER
1646	10

DATE MAILED: 10/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/041,615	CASMAN ET AL.	
	Examiner	Art Unit	
	Elizabeth C. Kemmerer, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

PART I: CATEGORIES OF INVENTIONS

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 38, 41, drawn to polypeptides and compositions/kits comprising same, classified in class 530, subclass 350, for example.

II. Claims 5-14, drawn to nucleic acids and vectors/cells comprising same, classified in class 536, subclass 23.1, for example.

III. Claims 15-18, 40, 43, drawn to antibodies and compositions/kits comprising same, classified in class 530, subclass 387.1, for example.

IV. Claims 19-21, 46, 47, drawn to methods comprising measuring amounts of nucleic acids via hybridization, classified in class 435, subclass 6, for example.

V. Claims 22-24, 50-52, drawn to methods comprising screening for agents that bind or modulates a polypeptide, classified in class 435, subclass 7.1, for example.

VI. Claim 25, drawn to method comprising contacting a polypeptide with a compound that binds it, classified in class 436, subclass 501, for example.

VII. Claims 26-29, 48, drawn to methods comprising administering a polypeptide to a patient, classified in class 514, subclass 2, for example.

VIII. Claims 30-33, 39, 42, drawn to gene therapy methods and products, classified in class 514, subclass 44, for example.

IX. Claims 34-37, 49, drawn to methods comprising administering an antibody to a patient, classified in class 424, subclass 130.1, for example.

X. Claims 44, 45, drawn to methods comprising measuring amounts of polypeptide in a sample, classified in class 435, subclass 7.2, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and each of V, VI, VII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used to isolate its binding partners, or to raise diagnostically useful antibodies.

Inventions II and each of IV and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can be used to make protein recombinantly in vitro.

Inventions III and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used to label or isolate the polypeptide which is its cognate antigen.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups I-III are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the protein of Group I can be prepared by processes which are materially different from recombinant DNA expression of Group II, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group II can be used other than to make the protein of Group I, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group I can be used in materially different methods other than to make the antibody of Group III, such as in therapeutic or diagnostic methods (e.g., in screening). Finally, although the antibody of Group III can be used to obtain the DNA of Group II, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The search for the three products are also non-coextensive, since the structures are not the same.

Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to

constitute patentably distinct inventions for the following reasons: Groups IV-X are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention IV requires search and consideration of quantification of nucleic acids, which is not required by any of the other groups. Invention V requires search and consideration of screening for agents that bind or modulate a polypeptide, which is not required by any of the other groups. Invention VI requires search and consideration of polypeptide binding interactions with other compounds, which is not required by any of the other groups. Invention VII requires search and consideration of polypeptide therapy, which is not required by any of the other groups. Invention VIII requires search and consideration of gene therapy, which is not required by any of the other groups. Invention IX requires search and consideration of antibody therapy, which is not required by any of the other groups. Invention X requires search and consideration of polypeptide quantification, which is not required by any of the other groups. Therefore, a search and examination of all of the methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

The remaining pairs of Inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are all product/process pairs. However, none of the processes of each pair requires use of the product of each pair.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and different classification, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder

in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

PART II: THE SEQUENCES

Further restriction to one of the following inventions is required under 35 U.S.C. 121:

A. Claims 1-52 (each in part), drawn to the claimed inventions as they recite SEQ D NOS: 1 and 2.

B. Claims 1-52 (each in part), drawn to the claimed inventions as they recite SEQ D NOS: 3 and 4.

C. Claims 1-52 (each in part), drawn to the claimed inventions as they recite SEQ D NOS: 5 and 6.

D. Claims 1-52 (each in part), drawn to the claimed inventions as they recite SEQ D NOS: 7 and 8.

E. Claims 1-52 (each in part), drawn to the claimed inventions as they recite SEQ D NOS: 9 and 10.

F. Claims 1-52 (each in part), drawn to the claimed inventions as they recite SEQ D NOS: 11 and 12.

G. Claims 1-52 (each in part), drawn to the claimed inventions as they recite SEQ D NOS: 13 and 14.

H. Claims 1-52 (each in part), drawn to the claimed inventions as they recite SEQ D NOS: 15 and 16.

I. Claims 1-52 (each in part), drawn to the claimed inventions as they recite SEQ D NOS: 17 and 18.

J. Claims 1-52 (each in part), drawn to the claimed inventions as they recite SEQ D NOS: 19 and 20.

K. Claims 1-52 (each in part), drawn to the claimed inventions as they recite SEQ D NOS: 21 and 22.

L. Claims 1-52 (each in part), drawn to the claimed inventions as they recite SEQ D NOS: 23 and 24.

M. Claims 1-52 (each in part), drawn to the claimed inventions as they recite SEQ D NOS: 25 and 26.

N. Claims 1-52 (each in part), drawn to the claimed inventions as they recite SEQ D NOS: 27 and 28.

O. Claims 1-52 (each in part), drawn to the claimed inventions as they recite SEQ D NOS: 29 and 30.

P. Claims 1-52 (each in part), drawn to the claimed inventions as they recite SEQ D NOS: 31 and 32.

Q. Claims 1-52 (each in part), drawn to the claimed inventions as they recite SEQ D NOS: 33 and 34.

APPLICANT IS ADVISED THAT THE REQUIREMENT TO ELECT A PAIR OF SEQUENCES IS NOT A REQUIREMENT FOR ELECTION OF SPECIES, RATHER, IT IS A FURTHER REQUIREMENT FOR ELECTION OF A GROUP.

The inventions are distinct, each from the other because of the following reasons: Each sequence requires its own search of the literature and sequence databases. A search and examination of all 34 sequences in one patent application would thus present the examiner with an undue search burden.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined (ONE FROM GROUPS I-X **AND** ONE FROM GROUPS A-Q) even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (703) 308-2673. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D. can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

ECK

Elyabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER